IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

Dianne M. Donaldson and Dale A. Donaldson,	)	
Plaintiffs,	)	
vs.	)	Case No. 3:15-cv-00014-DRH-DGW
Johnson & Johnson, a corporation; and Ethicon, Inc., a corporation,	)	
Defendants.	)	

COMPLAINT AND DEMAND FOR TRIAL BY JURY

Now come the Plaintiffs, Dianne M. Donaldson and Dale A. Donaldson, by Michael J. Meyer, their attorney, and complaining of the Defendants, Johnson & Johnson and Ethicon, Inc. state:

PARTIES, JURISDICTION AND VENUE

1. Plaintiffs, Dianne M. Donaldson and Dale A. Donaldson, are citizens of the State of Illinois.

2. Defendant, Johnson & Johnson, is a corporation existing under the laws of the State of New Jersey, with its principal place of business at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey.

3. Defendant, Ethicon, Inc., a subsidiary of Defendant, Johnson & Johnson, is a corporation existing under the laws of the State of New Jersey, with its principal place of business in Somerville, New Jersey. Defendant, Johnson & Johnson, and Defendant, Ethicon, will hereinafter collectively be referred to as Defendants.

4. Plaintiffs are seeking damages in excess of $75,000.00. Subject matter jurisdiction is proper pursuant to 28 U.S.C. § 1332.

5. Venue is proper in the Southern District of Illinois pursuant to 28 U.S.C. § 1391(a).

FACTUAL BACKGROUND

6. Defendants designed, manufactured, packaged, labeled, marketed, sold, and distributed the Gynecare TVT, including that which was implanted in Plaintiff, Dianne M. Donaldson, giving rise to Plaintiffs' claims asserted herein.

7. The TVT was offered in multiple variations, including, but not limited to, the TVT, TVT-O, and TVT-S, and all references to the TVT include the variations.

8. Plaintiff was implanted with the Gynecare TVT-S (hereinafter the "Product") during surgery performed by Dr. Michael Schultheis at St. Anthony's Memorial Hospital in Effingham, Effingham County, Illinois on May 24, 2010. .

9. The Product was implanted in Plaintiff to treat her stress urinary incontinence and anterior pelvic organ prolapse, uses for which the Product was designed, marketed and sold.

10. Due to the Product's defects as described herein, Plaintiff, Dianne M. Donaldson has suffered severe and permanent bodily injuries, significant mental and physical pain and suffering, and economic losses; and Plaintiff, Dale A. Donaldson, has suffered loss of consortium.

11. Defendants knew, or should have known, that the Product unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

12. The polypropylene material from which the Product is made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Product, including Plaintiff, Dianne M. Donaldson.

13. This negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the Product, such as those experienced by Plaintiff, Dianne M. Donaldson.

14. The Product was unreasonably susceptible to shrinkage and contraction inside the body.

15. The Product was unreasonably susceptible to "creep", a gradual elongation and deformation, when subject to prolonged tension in the body.

16. The Product has been marketed to the medical community and to patients as safe, effective, reliable medical devices, implanted by safe and effective, minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments.

17. Defendants omitted the risks, dangers, defects, and disadvantages of the Product, and advertised, promoted, marketed, sold

and distributed the Product as a safe medical device when Defendants knew or should have known that the Product would cause, and did cause, serious medical problems, and in some patients, including Plaintiff, Dianne M. Donaldson, catastrophic injuries.

18. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, the Product has high rates of failure, injury, and complications, fails to perform as intended, requires frequent and often debilitating re-operations, and has caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff, Dianne M. Donaldson.

19. The specific nature of the Product's defects includes, but is not limited to, the following:

a. the use of polypropylene material in the Product and the immune reaction that results from such material, causing adverse reactions and injuries;

b. the design of the Product to be inserted into and through an area of the body with high levels of bacteria that can adhere to the Product causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Product, including, but not limited to the propensity of the Product to contract or shrink inside the body that in turn causes surrounding tissue to be inflamed, become fibrotic, and

contract, resulting in injury;

d. the propensity of the Product to "creep" or to gradually elongate and deform when subject to prolonged tension inside the body;

e. the inelasticity of the Product, causing it to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted causing pain upon normal daily activities that involve movement in the pelvic region;

f. the propensity of the Product for degradation or fragmentation over time which causes a chronic inflammatory and fibrotic reaction and results in continuing injury over time.

20. The Product is also defective due to Defendants' failure to adequately warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. the Product's propensity to contract, retract, and/or shrink inside the body;

b. the Product's propensity for degradation, fragmentation and/or creep;

c. the rate and manner of mesh erosion or extrusion;

d. the risk of chronic inflammation resulting from the Product;

e. the risk of chronic infections resulting from the Product;

f. the risk of permanent vaginal or pelvic scarring as a result of the Product;

g. the risk of recurrent, intractable pelvic pain resulting from the Product;

h. the need for corrective or revision surgery to adjust or remove the Product;

i. the severity of complications that could arise as a result of implantation of the Product;

j. the hazards associated with the Product;

k. the Product's defects described herein;

l. treatment of stress urinary incontinence or prolapse with the Product is no more effective than feasible available alternatives;

m. treatment of stress incontinence or prolapse with the Product exposes patients to greater risk than feasible available alternatives;

n. treatment of stress urinary incontinence or prolapse with the Product makes future surgical repair more difficult than feasible available alternatives;

o. use of the Product puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

p. removal of the Product due to complications may involve

multiple surgeries and may significantly impair the patient's quality of life; and,

q. complete removal of the Product may not be possible and may not result in complete resolution of the complications, including pain.

21. Defendants have underreported information about the propensity of the Product to fail and cause injury and complications, and have made unfounded representations regarding the efficacy and safety of the Product through various means and media.

22. Defendants failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Product.

23. Defendants failed to design and establish a safe, effective procedure for removal of the Product, or to determine if a safe, effective procedure for removal of the Product exists.

24. Feasible and suitable alternatives to the Product have existed at all times relevant that do not present the same frequency or severity of risks as do the Product.

25. The Product was at all times utilized and implanted in a manner foreseeable to Defendants, as Defendants generated the instructions for use, created the procedures for implanting the device, and trained the implanting physicians.

26. Defendants provided incomplete and insufficient training and information to physicians regarding the use of the Product and the aftercare of patients implanted with the Product.

27. The Product implanted in Plaintiff was in the same or substantially similar condition as it was when it left Defendants' possession, and in the condition directed by and expected by Defendants.

28. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Product include, but are not limited to, erosion, contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, and chronic pelvic pain.

29. In many cases the women have been forced to undergo extensive medical treatment, including, but not limited to, operations to locate and remove the Product, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia, and that the Plaintiff, Dianne M. Donaldson has undergone or will undergo most, if not all, of said procedures.

30. At all relevant times herein, Defendants continued to promote the Product as safe and effective even when no clinical trials had been done supporting long or short-term efficacy.

31. Defendants failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Product.

32. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Product.

33. The Product as designed, manufactured, distributed, sold and supplied by Defendants was defective as marketed due to inadequate warnings, instructions, labeling and inadequate testing in the presence of Defendants' knowledge of lack of safety.

34. As a result of having the Product implanted in her, Plaintiff, Dianne M. Donaldson, has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and has undergone corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to obligations for medical services and expenses and lost income.

CAUSES OF ACTION: DIANNE M. DONALDSON

COUNT I: STRICT LIABILITY: NON-SPECIFIC DEFECT

35. Plaintiff, Dianne M. Donaldson, incorporates by reference paragraphs 1 through and including 34 of this Complaint as fully as if set forth herein.

36. The Product was unreasonably dangerous at the time it left the control of the Defendants in that it failed to perform in a manner reasonably to be expected in light of its nature and intended function.

37. The product was implanted in the Plaintiff and used in the manner expected, promoted, and directed by the Defendants.

38 There was no reasonable cause for the Product's failure to perform other than the Product's defective nature.

39. As a direct and proximate result of the unreasonably dangerous condition of the Product, Plaintiff has sustained severe and permanent injury, has experienced and will in the future experience physical and emotional pain and suffering, has experienced loss of a normal life, has become disabled, and has incurred and will in the future incur the reasonable expense of necessary medical care.

WHEREFORE, Plaintiff, Dianne M. Donaldson, demands judgment against Defendants for compensatory and punitive damages in an amount exceeding $75,000.00 and costs.

PLAINTIFF DEMANDS A TRIAL BY JURY.

Dianne M. Donaldson, Plaintiff

By s/ Michael J. Meyer
Michael J. Meyer
Her Attorney

COUNT II: STRICT LIABILITY: DESIGN DEFECT

40. Plaintiff, Dianne M. Donaldson, incorporates by reference paragraphs 1 through and including 34 of this Complaint as fully as if set forth herein.

42. The Product implanted in Plaintiff was not reasonably safe for its intended use and was defective as described herein with respect to its design. As previously stated, the Product's design defects include, but are not limited to:

a. the use of polypropylene material in the Product and the immune reaction that results from such material, causing adverse reactions and injuries;

b. the design of the Product to be inserted into and through an area of the body with high levels of bacteria that adhere to the Product causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical defects with the design of the Product, including, but not limited to, the propensity of the Product to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become

fibrotic, and contract, resulting in injury;

d. the propensity of the Product to "creep", or to gradually elongate and deform when subject to prolonged tension inside the body.

e. the inelasticity of the Product, causing it to be improperly mated to the delicate and sensitive areas of the pelvis where it is implanted, and causing pain upon normal daily activities that involve movement in the pelvis;

f. the propensity of the Product for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time.

43. As a direct and proximate result of the Product's aforementioned defects, Plaintiff has sustained severe and permanent injury, has experienced and will in the future experience physical and emotional pain and suffering, has experienced loss of a normal life, has become disabled, and has incurred and will in the future incur the reasonable expense of necessary medical care.

WHEREFORE, Plaintiff, Dianne M. Donaldson, demands judgment against Defendants for compensatory and punitive damages in an amount exceeding $75,000.00 and costs.

PLAINTIFF DEMANDS A TRIAL BY JURY.

Dianne M. Donaldson, Plaintiff

By s/ Michael J. Meyer
Michael J. Meyer

COUNT III: STRICT LIABILITY: FAILURE TO WARN

44. Plaintiff, Dianne M. Donaldson, incorporates by reference paragraphs 1 through and including 34 of this Complaint as fully as if set forth herein.

45. The Product implanted in Plaintiff was not reasonably safe for its intended use and was defective as described herein due to its lack of appropriate and necessary warnings. Specifically, Defendants did not provide sufficient or adequate warnings regarding, among other subjects:

a. the Product's propensity to contract, retract, and shrink inside the body;

b. the Product's propensity for degradation, fragmentation and creep;

c. the Product's inelasticity preventing improper mating with the pelvic floor and vaginal region;

d. the rate and manner of erosion or extrusion;

e. the risk of chronic inflammation resulting from the Product;

f. the risk of chronic infections resulting from the Product;

g. the risk of permanent vaginal or pelvic scarring as a result

of the Product;

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Product;

i. the need for corrective or revision surgery to adjust or remove the Product;

j. the severity of complications that could arise as a result of implantation of the Product;

k. the hazards associated with the Product;

l. the Product's defects described herein;

m. treatment of stress urinary incontinence or prolapse with the Product is no more effective than feasible available alternatives;

n. treatment of stress urinary incontinence or prolapse with the Product exposes patients to greater risk than feasible available alternatives;

o. treatment of stress urinary incontinence or prolapse with the Product makes future surgical repair more difficult than feasible available alternative;

p. use of the Product puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. removal of the Product due to complications may involve multiple surgeries and may significantly impair the

patient's quality of life; and,

r. complete removal of the Product may not be possible and may not result in complete resolution of the complications, including pain.

46. As direct and proximate result of the failures to warn as described herein, Plaintiff has sustained severe and permanent injury, has experienced and will in the future experience physical and emotional pain and suffering, has experienced loss of a normal life, has become disabled, and has incurred and will in the future incur the reasonable expense of necessary medical care.

WHEREFORE, Plaintiff, Dianne M. Donaldson, demands judgment against Defendants for compensatory and punitive damages in an amount exceeding $75,000.00 and costs.

PLAINTIFF DEMANDS A TRIAL BY JURY.

Dianne M. Donaldson, Plaintiff

By s/ Michael J. Meyer
Michael J. Meyer
Her Attorney

CAUSE OF ACTION: DALE A.DONALDSON

COUNT IV: LOSS OF CONSORTIUM

47. Plaintiff, Dale A. Donaldson, incorporates by reference paragraphs 1 through and including 46 of this Complaint as fully as if set forth herein.

48. At all times mentioned herein the Plaintiff, Dale A. Donaldson was and continues to be the lawfully wedded spouse of Dianne M. Donaldson.

49. As a direct and proximate result of the injuries to his spouse as aforesaid, the Plaintiff, Dale A. Donaldson, has lost and will in the future lose services of, and society and companionship with, his wife.

WHEREFORE, Plaintiff, Dale A. Donaldson, demands judgment against Defendants for compensatory and punitive damages in an amount exceeding $75,000.00 and costs.

PLAINTIFF DEMANDS A TRIAL BY JURY.

Dale A. Donaldson, Plaintiff

By s/ Michael J. Meyer
Michael J. Meyer
His Attorney

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